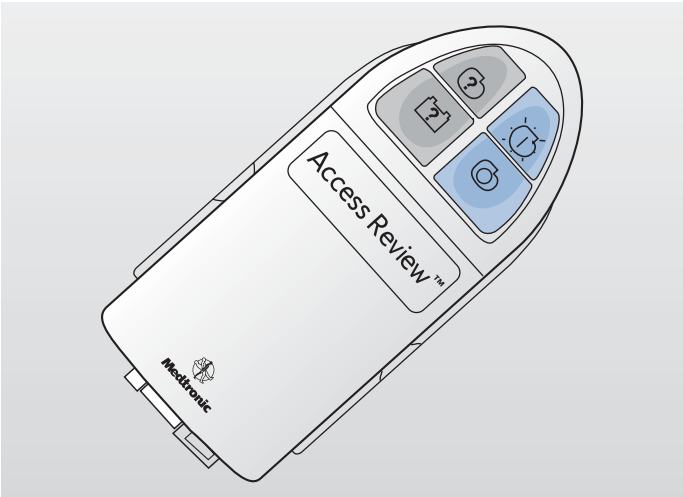
Medtronic

ACCESS REVIEW™ THERAPY CONTROLLER 7438 USER MANUAL



! USA Rx only

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Access Review™ is a trademark of Medtronic, Inc.

! USA FCC Information

The following is federal government communications regulation information about the Access Review Model 7438 Therapy Controller.

FCC ID: LF57434A

This device complies with Part 15 Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

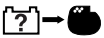
IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

Key contact information

Doctor	
Nurse	
Clinic	
Telephone	
Hospital	

Label symbols

Explanation of symbols on products and packaging. Refer to the appropriate product to see symbols that apply.

Keypad Symbols		Indicator Light Symbols	
	Neurostimulator on		Neurostimulator on
	Neurostimulator off		Neurostimulator off
	Neurostimulator on/off status		Neurostimulator battery
	Neurostimulator battery status		Therapy controller battery

Beeper Volume Control Switch Symbols	
	Volume off
	Low volume
	High volume

Miscellaneous Symbols

Positioning symbol

Caution, consult accompanying documents

Consult instructions for use

Manufacturer

Temperature limitation

Serial number

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC and R&TTE Directive 1999/5/EC.

Authorized Representative of the European Community

For U.S. audiences only.

IEC 60601-1/EN 60601-1, Type BF Equipment

Non-ionizing electromagnetic radiation

System meets the applicable Canadian [C22.2-601.1-M90 (R2001)] electrical safety standard requirements.

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)

Antenna jack

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Glossary

Beeper volume control switch – Located under the front cover. It lets you turn the beeper off or set the volume to low or high.

Command signals – Signals sent from the therapy controller to the neurostimulator that can control the function of the neurostimulator.

Electromagnetic interference (EMI) – A field of energy made by equipment found in the home, work, medical, or public environments that is strong enough to interfere with the operation of your therapy controller.

Indicator lights – Located on the back of the therapy controller. They tell you whether the neurostimulator is on or off, the neurostimulator battery status, and the therapy controller battery status.

Neurostimulator – The implanted device that contains a battery and electronics to control stimulation.

Status signals – Signals sent from the neurostimulator to the therapy controller. These signals are received by the therapy controller, and the neurostimulator status is “reported” using a beeper and lights.

Therapy controller – A portable hand-held device that may be used to turn on and turn off your neurostimulator.

1 Introduction

How to use this manual

Refer to this manual after you receive an implanted neurostimulator. Ask your clinician to explain anything that is unclear.

- A glossary is provided to describe terms that may be unfamiliar to you.
- Chapter 1, “Introduction,” describes what the therapy controller does and the components of the therapy controller. It also provides general precautions related to using your therapy controller.
- Chapter 2,”Using the therapy controller,” includes instructions for how to place the controller over the neurostimulator; how to turn the neurostimulator on or off; how to check whether the neurostimulator is on or off; and how to check the neurostimulator battery.
- Chapter 3, “Troubleshooting,” describes therapy controller warning and information screens, how to solve possible problems, and who to contact if your device is lost or broken.

- Chapter 4,”Maintenance,” describes how to care for your therapy controller and system specifications.

For important safety information

Please see your Patient Therapy guide provided with your therapy controller for important safety information, related warnings and precautions, and additional information about your therapy.

Purpose of the therapy controller

The Access Review Therapy Controller is a portable, hand-held device intended for use with your implanted Soletra neurostimulator. The controller is used to:

- turn the neurostimulator on or off,
- check the neurostimulator on or off status,

- check the status of the neurostimulator battery,
- check the status of the therapy controller battery, and
- confirm that the neurostimulator has received information from the therapy controller.

Purpose of the implanted brain stimulation system

Refer to the therapy-specific patient manual for the purpose of your implanted brain stimulation system and a description of the components.

Precautions

Other implanted medical devices – If you also have another implanted device (such as a pacemaker or defibrillator), make sure the therapy controller is held only over the neurostimulator. This prevents the radio signals (telemetry) from the therapy controller from interfering with how the other implanted device works.

Therapy controller use – The device is not certified for use in the presence of a flammable or anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the device near flammable atmospheres are unknown.

Therapy controller modification – Do not modify this equipment. Modification of this equipment can result in damage to the programmer, causing the programmer to malfunction or become unusable.

Communication interference from EMI – When using your therapy controller to communicate with your neurostimulator,

move away from equipment that may generate electromagnetic interference (EMI) or turn off the likely source of EMI. EMI may disrupt communication between the therapy controller and neurostimulator. Examples of EMI sources are computer monitors, cellular telephones, and motorized wheelchairs. For more information about EMI, refer to your therapy-specific patient manual.

How the therapy controller works

> **Note:** You can turn on your therapy controller by touching any of the function keys. The controller functions whenever a key is pressed as long as a working battery is properly installed. If another key is not pressed within 8 seconds, the controller will turn off.

When you place the therapy controller over your neurostimulator and press a key on the keypad, the therapy controller sends a command signal to the neurostimulator.

When the neurostimulator receives a command signal, the therapy controller gives you two kinds of feedback:

- **Indicator lights –** Found on the back of the controller. They stay lit for 5 – 8 seconds after receiving a signal.
- **Beeps –** If the beeper is turned on, the therapy controller beeps when a change has occurred.

Therapy controller components

The therapy controller components are shown in Figure 1.1.

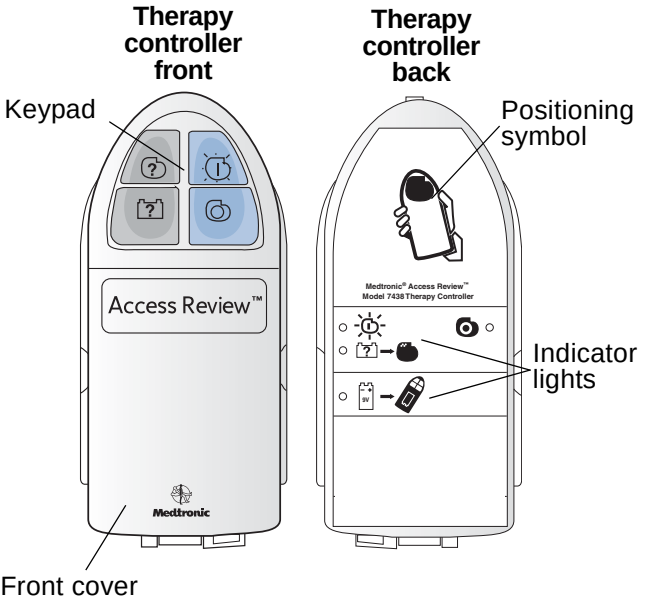

Figure 1.1 The Access Review Therapy Controller.

Keypad

The keypad has keys for turning the neurostimulator on or off, checking whether the neurostimulator is on or off, and checking the neurostimulator battery status (Figure 1.2).

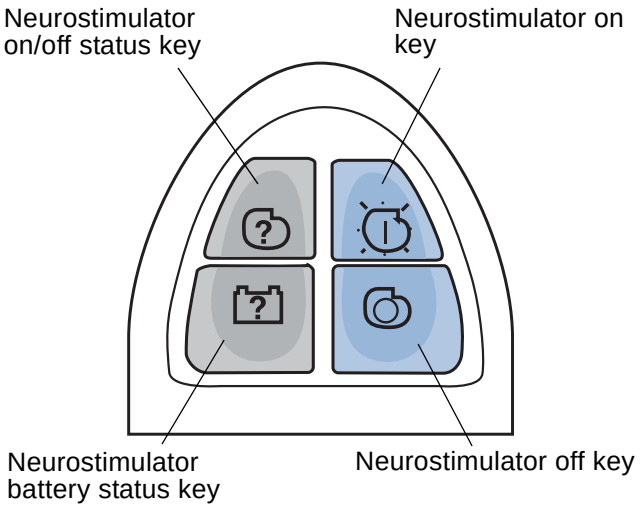

Figure 1.2 The keypad.

Symbols and indicator lights

The back of the therapy controller displays symbols and indicator lights.

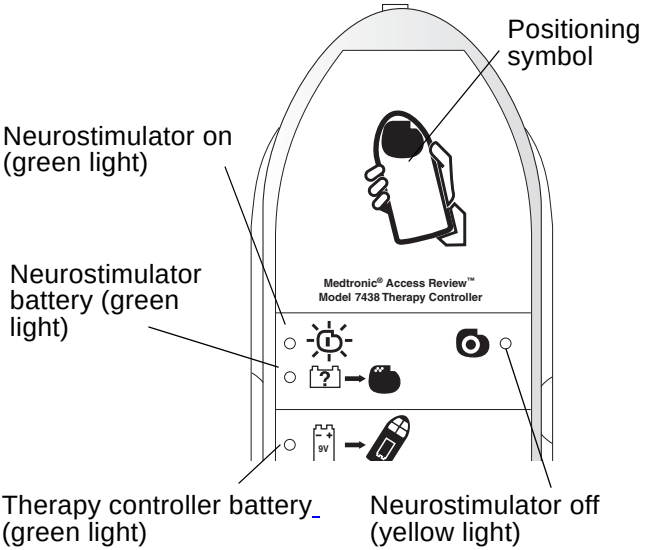

Figure 1.3 Symbols and indicator lights.

Symbols

The positioning symbol helps you correctly place the therapy controller over your neurostimulator.

Indicator lights

When the neurostimulator receives a command signal, the indicator lights show:

- Neurostimulator on or off status
- Neurostimulator battery status
- Therapy controller battery status

Table 1.1 explains what the indicator lights mean. Refer to Chapter 2 on page 35 for more complete information about how to use the therapy controller and how to analyze the indicator lights.

Table 1.1 Indicator light descriptions.

When:	It means:
light is lit.	Neurostimulator is on.
light is lit.	Neurostimulator is off.
is lit.	Neurostimulator battery is OK.
is blinking.	Neurostimulator battery is low. **Contact your clinician immediately.**
is not lit.	Move to another room, check the therapy controller battery, reposition the therapy controller, and try again. (Interference from electrical equipment may be causing the light to remain off.) **If the light remains off, contact your clinician immediately.**
is lit.	Controller battery is OK.
is blinking.	Controller battery is low. **Replace with new 9-volt alkaline battery.**
is not lit.	Controller battery is depleted. **Replace with new 9-volt alkaline battery.**

Front cover

These components are found under the front cover. You need to remove the cover to access them.

- Identification label (see page 28)
- **Beeper volume control** switch (see page 30)
- Therapy controller battery (see page 60)

To remove the front cover

1. Lift the cover release tab on the end of the therapy controller and lift off the cover.

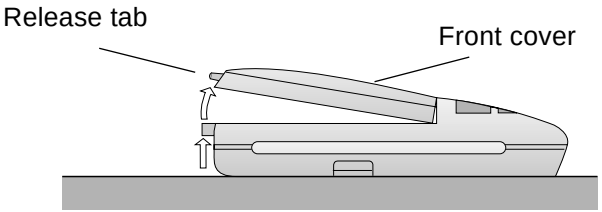

Figure 1.4 Remove the front cover.

To replace the front cover

1. Insert the front cover tabs into the slots on the therapy controller (Figure 1.5).
2. Press down on the end of the cover to lock it in place.

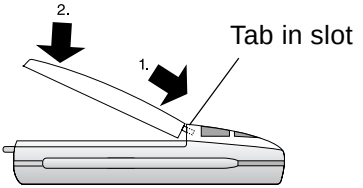

Figure 1.5 Replace the front cover.

Identification label

The therapy controller has an identification label that you need to complete and apply to the inside front cover.

1. Remove the front cover (see page 27).
2. Write the information (your name, phone number, etc.) on the label with permanent ink.

3. Peel off the backing and stick the label to the underside of the front cover (Figure 1.6).

   Note: Do not place the identification label over the ridges on the cover.

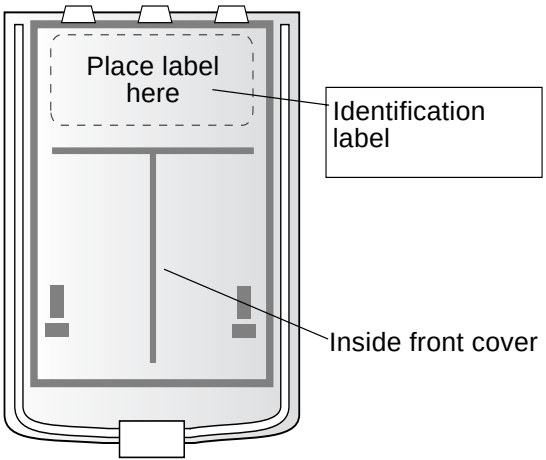

Figure 1.6 Placement of the identification label inside the front cover.

4. Replace the front cover (see page 28).

Beeper volume control switch

The **Beeper volume control** switch is located under the front cover (Figure 1.7). When the switch is set to low or high, the therapy controller beeps each time the neurostimulator receives a command signal.

Turning the beeper off prevents you from hearing the status indications. Turning the beeper off is not recommended.

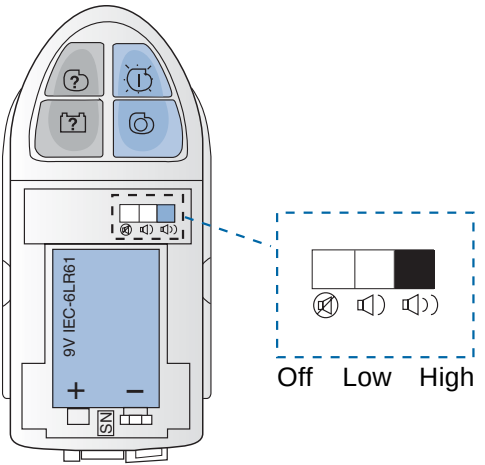

Figure 1.7 **Beeper volume control** switch set to **High** (with cover removed).

Table 1.2 Beeper descriptions.

If you hear:	It means:
One beep	• You pressed a therapy controller key and the signal was successfully received by the neurostimulator.
Multiple beeps	• You held a key down for an extended time. After releasing the key, the indicator lights reflect the last accepted communication between the therapy controller and the neurostimulator.
No beeps	• The **Beeper volume control** switch may be in the **Off** position. • See “Troubleshooting” on page 47 for other possible explanations and actions.

Accessories

Wrist strap

A wrist strap is packaged with the therapy controller. Using the wrist strap can help you avoid dropping the controller. Attach the wrist strap to the therapy controller on the loop near the cover release tab.

Figure 1.8 Wrist strap attachment.

Carrying case

A carrying case is included with the controller. Store the therapy controller in the carrying case to protect it.

Battery

A 9-volt battery that provides power for your therapy controller is also included. See “Therapy controller batteries” on page 60 for more information on checking and replacing the battery.

2 Using the therapy controller

This section includes step-by-step instructions for the following activities:

- Placing the therapy controller over the neurostimulator
- Turning the neurostimulator on or off
- Checking the neurostimulator on/off status
- Checking the neurostimulator battery

Placing the therapy controller over the neurostimulator

The therapy controller must be placed directly over the neurostimulator for the devices to send signals to each other.

1. Locate the neurostimulator under your skin.
2. Place the positioning symbol on the back of the therapy controller over the neurostimulator.

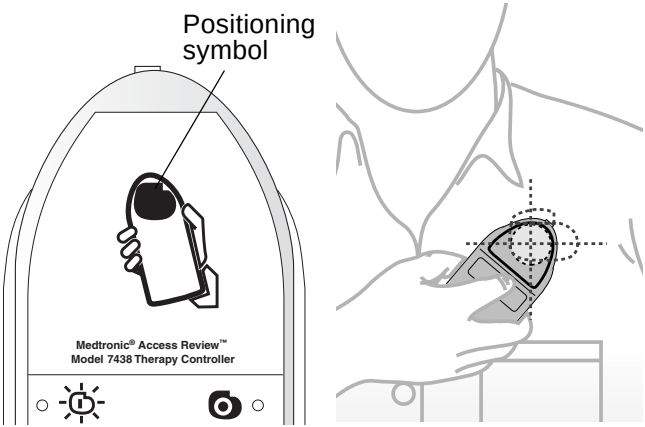

Figure 2.1 Place the controller over the neurostimulator.

3. Hold the therapy controller steady and flat against your skin or clothing while pressing the desired key.

   Note: When the neurostimulator receives a command signal, the therapy controller gives you two kinds of feedback:

   – Indicator lights

     Found on the back of the controller. They stay lit for 5 – 8 seconds after receiving a signal.

– Beeps

  If the beeper sound is turned on, the therapy controller beeps when a change has occurred.

Turning the neurostimulator on or off

Patients should turn on and turn off their neurostimulator as advised by their clinician.

To turn the neurostimulator on

1. Place the therapy controller over your neurostimulator (see page 36).
2. Press the **Neurostimulator on** key. Listen for the confirmation beep.

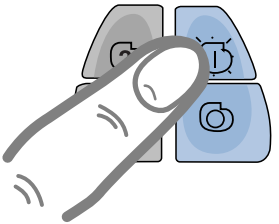

Figure 2.2 **Neurostimulator on** key.

3. Check that the green **Neurostimulator on** light is lit on the back of the controller.

To turn the neurostimulator off

1. Place the therapy controller over your neurostimulator (see page 36).
2. Press the **Neurostimulator off** key. Listen for the confirmation beep.

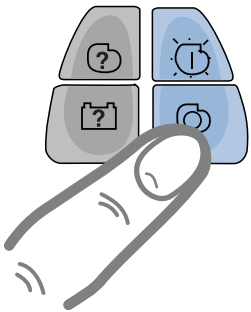

Figure 2.3 **Neurostimulator off** key.

3. Check that the yellow **Neurostimulator off** light is lit on the back of the controller.

Notes:

- The yellow light means that the neurostimulator is turned off. Verify that you intended the neurostimulator to be in off mode.
- If neither of the lights are lit, refer to “Troubleshooting” on page 47.

Checking the neurostimulator on/off status

The therapy controller can help you determine whether your neurostimulator is on or off.

1. Place the therapy controller over your neurostimulator (see page 36).
2. Press the **Neurostimulator on/off status** key. Listen for the confirmation beep.

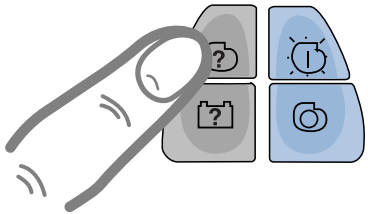

Figure 2.4 **Neurostimulator on/off status** key.

Note: Pressing the **Neurostimulator on/off status** key does not turn the device on or off; it only determines the current status of your neurostimulator.

3. Look at the back of the controller to see whether the green **Neurostimulator on** light or the yellow **Neurostimulator off** light is lit.

Table 2.1 Neurostimulator on/off lights.

When this happens:	It means:
light is lit.	Neurostimulator is on.
light is lit.	Neurostimulator is off.
Neither light is lit.	Refer to “Troubleshooting” on page 47.

Checking the neurostimulator battery

You can use the therapy controller to check the current status of your neurostimulator battery. Your clinician will tell you how often to check the status.

Note: The status of your neurostimulator battery can change quickly, depending on the current drainage of your battery. Do not rely on this light to predict the longevity of your battery. It is important to attend your regular follow-up visits as your clinician can use a clinician programmer to more accurately calculate your neurostimulator battery life.

To check the neurostimulator battery

1. Place the therapy controller over your neurostimulator (see page 36).
2. Press the **Neurostimulator battery status** key. Listen for the confirmation beep.

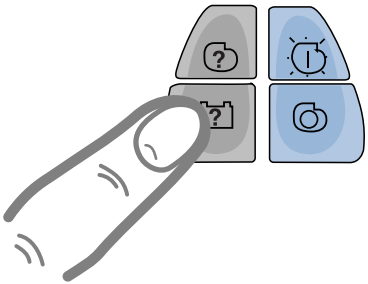

Figure 2.5 **Neurostimulator battery status** key.

3. Check the **Neurostimulator battery** light on the back of the controller.

Table 2.2 Neurostimulator battery light.

When the light is:	It means:
Lit	Neurostimulator battery is OK.
Blinking	Neurostimulator battery is low. **Contact your clinician immediately.**
Not lit	Move to another room, check the therapy controller battery, reposition the therapy controller, and try again. (Interference from electrical equipment may be causing the light to remain off.) **If the light remains off, contact your clinician immediately.**

3 Troubleshooting

Possible problems and solutions

Table 3.1 will help you solve problems or identify when to call your clinician. Problems are described in the left column. The right column lists possible causes of the problem (plain text) and how to correct the problem (**bold blue text**).

If there is more than one explanation/action, do the first action listed. If that doesn't solve the problem, proceed down the list.

> **Note:** If your problem is not solved after several attempts, or if your problem is not described here, contact your clinician. If your clinician thinks there is a problem with your therapy controller, contact Medtronic (refer to "Service" on page 66).

Table 3.1 Troubleshooting

Problem	Explanation and Action
No lights turn on when you send a command signal to your neurostimulator.	No battery or depleted battery in the therapy controller. **Replace the battery; use a new 9-volt alkaline battery.** Sunlight may be preventing your viewing of the indicator lights. **If you are outdoors, move indoors or into the shade.** You waited longer than 8 seconds to check the indicator lights. **Try again. This time, look at the lights before 8 seconds have elapsed.** The temperature conditions may be outside those specified for the therapy controller. **Refer to “Specifications” on page 69.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
The Therapy controller battery light turns on, but none of the other lights are on.	The therapy controller is not positioned correctly over the neurostimulator. **Reposition the controller and try again.** The therapy controller was removed from the neurostimulator too soon. **Hold the controller over the neurostimulator for at least 1 second after pressing a key.** Electromagnetic interference (EMI) from appliances, computers, machinery, large speakers, gasoline engines, etc, may be affecting the controller. (Refer to your therapy-specific patient manual for detailed information on EMI and EMI effects on therapy.) **Move to a different room and try again.** The neurostimulator battery is depleted. When the neurostimulator battery is depleted, therapy is no longer available. **Contact your clinician immediately.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
The Neurostimulator battery light is blinking, or it has been blinking and is now off.	The neurostimulator battery is low or depleted. When the neurostimulator battery is depleted, therapy is no longer available. **Contact your clinician immediately.**
You want to check the neurostimulator without changing the setting.	**If you do not know whether the neurostimulator is on or off, press the Neurostimulator on/off status key. The appropriate light should be lit on the back of the controller.** **For information on the neurostimulator's battery status, refer to "Neurostimulator on/off lights." on page 42.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
The indicator lights do not flash and the beeper does not beep when a new battery is installed.	The therapy controller failed its self-test. **Remove the battery, and insert a new 9-volt alkaline battery. The indicator lights should flash and you should hear one beep. If this does not occur, contact your clinician.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
The beeper does not sound. Only the Therapy controller battery light is on.	The beeper is not on. **Set the Beeper volume control switch to low or high and listen to be sure it is working.** The therapy controller is not positioned correctly over the neurostimulator. **Reposition the controller and try again.** The controller was removed from the neurostimulator too soon. **Hold the controller over the neurostimulator for at least 1 second.** Electromagnetic interference (EMI) from appliances, computers, machinery, large speakers, gasoline engines, etc, may be affecting the controller. (Refer to your therapy-specific patient manual for detailed information on EMI and EMI effects on therapy.) **Move to a different room and try again.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
The neurostimulator will not turn on.	The therapy controller is not positioned correctly over the neurostimulator. **Reposition the controller and try again.** The therapy controller was removed from the neurostimulator too soon. **Hold the controller closer to the neurostimulator, line up the positioning symbol and try again. Hold the controller over the neurostimulator for at least 1 second. The therapy controller should beep and the green Neurostimulator on light should be lit for 5 – 8 seconds after the key press. Try again.** The neurostimulator battery is depleted. When the neurostimulator battery is depleted, therapy is no longer available. **Contact your clinician immediately.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
Your therapy controller does not respond to key presses.	No battery or depleted battery in the therapy controller. **Replace the battery; use a new 9-volt alkaline battery.**
You spilled fluid on the therapy controller.	**Dry it with a towel.**

Table 3.1 Troubleshooting (continued)

Problem	Explanation and Action
The therapy controller fell into water.	1. Remove the therapy controller from the water. 2. Wipe it with a towel dampened with clean tap water. 3. Remove the battery cover and battery. 4. Dry the battery compartment with a towel. 5. Allow the battery compartment to dry at room temperature for as long as possible (24 hours recommended). 6. Replace the battery. 7. Shake the therapy controller; if you hear water inside, or if it doesn't work properly, contact Medtronic (see "Service" on page 66).
The controller falls off a cabinet or table.	**Try the controller; it should work. If it doesn't work, contact Medtronic (see "Service" on page 66).**

Therapy controller assistance

The therapy controller has been designed and tested to provide trouble-free service. If repair or service is needed, contact your clinician or a Medtronic sales office. Refer to the Medtronic contacts at the end of this manual.

The serial number is located in the battery compartment. This number identifies each therapy controller. If you contact Medtronic about your therapy controller, refer to the serial number.

- If your therapy controller stops working, first try the steps in “Troubleshooting” on page 49. Contact your clinician if indicated by the troubleshooting information or if you need additional assistance.
- If you lose your therapy controller, contact your clinician to order a new therapy controller.

! USA **Note:** To register the therapy controller for service covered by the warranty, complete and mail the warranty registration.

4 Maintenance

This chapter describes how to care for and dispose of your therapy controller and accessories.

Therapy controller batteries

A 9-volt alkaline battery is the power source for the therapy controller.

> **Note: Make sure a fresh 9-volt alkaline battery is always available.** This ensures that you can always turn on or turn off your therapy. Typically, at least 3 months of use can be expected from a new alkaline battery.

△ **Caution:** The therapy controller is designed to indicate battery status with an alkaline battery installed. Other battery types may not give an accurate indication of the therapy controller's battery status.

△ **Caution:** If you think you will not be using the therapy controller for more than 4 weeks, remove the battery. A battery left in

the device may corrode, causing damage to the electronic components.

Checking the therapy controller battery

1. Hold the therapy controller away from your neurostimulator so that you do not send a command signal to the neurostimulator.
2. Press any key on the therapy controller keypad.
3. Check the **Therapy controller battery** light on the back of the controller.

Table 4.1 **Therapy controller battery** light.

When the light is:	It means:
Lit	Controller battery is OK.
Blinking	Controller battery is low. **Replace with new 9-volt alkaline battery.**
Not lit	Controller battery is depleted. **Replace with new 9-volt alkaline battery.**

Replacing the therapy controller battery

To remove the therapy controller battery

1. Remove the front cover (see page 27).
2. Place one finger on the edge of the battery near the **Beeper volume control** switch.
3. Lift the battery out of the compartment without using excessive force.

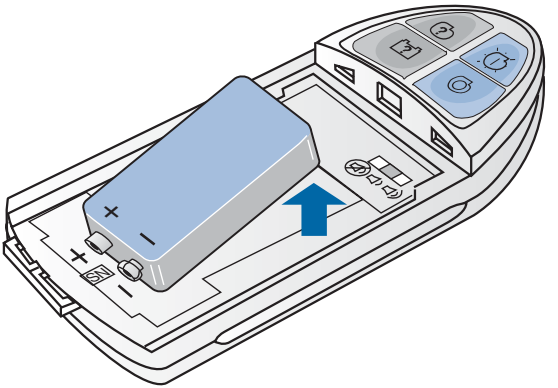

Figure 4.1 Remove the battery.

To insert the therapy controller battery

1. Insert the battery and listen for a beep:

   a. Match the positive (+) and negative (–) contacts on the battery with the same symbols on the controller.

   b. Press the battery down into the battery compartment without using excessive force. Do not press any keys on the front of the controller while inserting the battery.

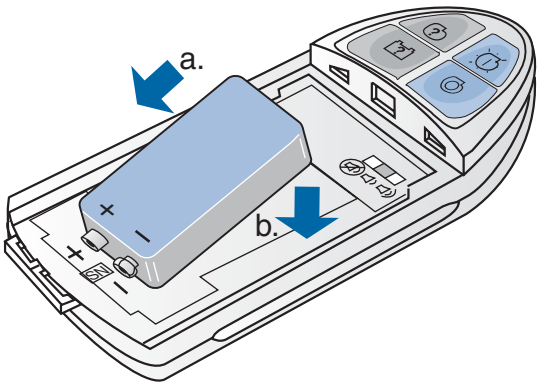

Figure 4.2 Insert the battery.

2. Replace the front cover (see page 28).
3. Check the therapy controller battery status (see page 61).

   Notes:

   – When the battery is installed correctly, the therapy controller beeps and all of the indicator lights flash briefly.

   – If you did not hear a beep when you inserted the battery, remove the battery and reinsert it.

Cleaning and care

- Handle your therapy controller with care.
- Do not take apart or tamper with the therapy controller; this could affect how it works.
- Protect the therapy controller from sharp blows or physical shocks.
- Replace low or depleted batteries to ensure that the therapy controller works properly.

△ **Caution:** If you think you will not be using the therapy controller for more than 4 weeks, remove the battery. A battery left in the device may corrode, causing damage to the electronic components.

- Clean the battery contacts periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Your therapy controller is not waterproof. Do not allow moisture to get inside it.

△ **Caution:** Do not immerse the therapy controller in liquid. Do not clean it with bleach, nail polish remover, or similar substances. Immersing the therapy controller in liquid or cleaning it with bleach, nail polish remover, or a similar substance can make the therapy controller nonfunctional.

- Clean the outside of the therapy controller with a slightly damp cloth. Mild household cleaners will not damage the case or labels.
- Table 4.2 on page 69 shows the optimal environmental conditions for operating your therapy controller. If your therapy controller is not working, check Table 4.2 to see if the cause might be related to environmental conditions.

Service

The Access Review Therapy Controller has been designed and tested to provide long, trouble-free service. If repair or service is needed, contact Medtronic. Refer to the

contact information at the end of this manual.

! USA To register the therapy controller for service covered by the warranty, complete and mail the warranty registration card.

A serial number, printed on a label under the battery, identifies each Access Review Therapy Controller. If you write or call Medtronic about your therapy controller, refer to the serial number.

Battery and therapy controller disposal

Dispose of depleted batteries and worn out devices according to local requirements. If you no longer need your therapy controller and would like to donate it, contact your clinician.

Neurostimulator disposal

The implanted device should be removed before burial or cremation. In some countries, removal of battery-powered

implantable devices is required before burial because of environmental concerns. Also, the device should be removed before cremation. The cremation process causes the battery to explode. Explanted devices should not be resterilized or reimplanted.

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment, and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact Medtronic. Refer to the contact information at the end of this manual.

Specifications

Table 4.2 Therapy controller specifications.

Item	Specification
Power source	9-volt alkaline battery (type 6LR61 or 6F22E)
Battery life	3 months (average)
Operating temperature	+9 to +43°C (+49 to +110°F)
Storage temperature	-40 to +65°C (-40 to +149°F)
Controller size	Approximately 13.5 x 6.1 x 3.0 cm (5.3 x 2.4 x 1.2 in)
Controller weight	Approximately 170 g (6 oz)

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